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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* RYOTA SUGIMOTO

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Appeal 2009-003720  
Application 09/870,672  
Technology Center 3700

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Decided: September 30, 2009

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Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and  
FRANCISCO C. PRATS, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 4, 5, 9-20, 22, 23, and 32-45, directed to an implantable tubular device. We have jurisdiction under 35 U.S.C. § 6(b).

## STATEMENT OF THE CASE

The present invention is directed to “an implantable tubular device, for example, a stent, having a deformable portion to improve the flexibility of an annular unit of the device so that the device can pass easily through a bent portion of the human body” (Spec. 2: 6-9). The deformable portion comprises “substantially annular grooves” on the inner and/or outer surfaces of the device that form “an endless annular configuration” or a spiral configuration when prolonged (*id.* at 9: 23-27; 10: 29 to 11: 2; 12: 27).

Claim 1 is representative of the subject matter on appeal:

1. An implantable tubular device formed substantially tubular and having a deformable portion formed on a peripheral surface thereof and including wavy annular members with bent portions, with said deformable portion forming a predetermined angle with respect to an axial direction of said device and when the deformable portion is prolonged it forms an endless annular configuration, said deformable portion being easy to deform in comparison with a remainder part of said device, said deformable portion being formed in a plural number, and, said deformable portions being formed as grooves having a bottom surface provided on an inner surface of said tubular device which faces inwardly toward an interior of said tubular device, on an outer surface of said tubular device which faces away from the interior of the tubular device or on both the inner and outer surfaces of said tubular device, and the deformable portions being formed on the bent portions of the wavy annular members such that the deformable portions are substantially parallel with one another.

The Examiner relies on the following evidence:

Alt et al.	US 5,788,979	Aug. 4, 1998
Shanley	US 6,293,967 B1	Sep. 25, 2001
Palmaz	WO 99/23977	May 20, 1999

Claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shanley and Palmaz; while claims 14-19, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shanley, Palmaz, and Alt.

We reverse.

#### ISSUE

Claim 1 is directed to an implantable tubular device comprising wavy annular members with bent portions, wherein the device has grooves on its inner and/or outer surfaces, and wherein the grooves, when prolonged, form an endless annular configuration. Independent claim 32 is similar to claim 1 but recites that the grooves form a spiral configuration.

The Examiner finds that Shanley discloses “an implantable tubular device . . . including wavy annular members arranged in an axial direction of the device with bent portions,” but doesn’t disclose grooves on the device (Office Action mailed January 25, 2005, p. 2).<sup>1</sup> However, the Examiner finds that Palmaz teaches that “a variety of different groove patterns may be utilized” on a similar implantable device “in order to aid in migration of cells” (*id.* at p. 3), and further teaches that “the grooves may be placed anywhere” on the device (*id.*). The Examiner concluded that it would have been obvious to “provide the stent, including the annular wavy portions and free bent portions of Shanley with grooves as taught by Palmaz in order to

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<sup>1</sup> Appellant’s Brief on Appeal refers to the Final Rejection mailed September 7, 2005 for the statement of the rejections; the Final Rejection, in turn, refers to the Office Action mailed January 25, 2005 for the statement of the rejections.

aid in migration of cells” (*id.*), and some of the groove patterns would inherently produce a spiral-like or annular configuration (*id.*).

Appellant contends that the references, whether “alone or in combination with each other,” don’t disclose “grooves located on a bent portion of a wavy annular member” (App. Br. 8),<sup>2</sup> or “deformable portions being formed as grooves and when the deformable portion is prolonged it forms an endless annular configuration” (*id.* at 7) or “a spiral configuration” (*id.* at 8).

In light of these conflicting positions, the issue raised by both rejections is the same: Has the Examiner established that the combined teachings of Shanley and Palmaz would have suggested providing grooves on an implantable tubular device comprising wavy annular members with bent portions, in such a way that the grooves, when prolonged, form an endless annular configuration or a spiral configuration?

#### FINDINGS OF FACT

##### *The Invention*

FF1 Independent claim 1 is directed to an “implantable tubular device . . . having a deformable portion formed on a peripheral surface thereof and including wavy annular members with bent portions” wherein the deformable portion is a groove “formed in a plural number” on the inner and/or outer surfaces of the device, and wherein “when the deformable portion is prolonged it forms an endless annular configuration” (claim 1). Independent claim 32 is similar to claim 1, but recites that the deformable portion, when prolonged, forms a “spiral configuration” (claim 32).

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<sup>2</sup> All references to Appellant’s Brief on Appeal are to the Substitute Brief filed December 5, 2006.

FF2 Figure 2 of the Specification, reproduced in part immediately below, illustrates an embodiment of the invention that meets the limitations of claim 1:

FIG. 2

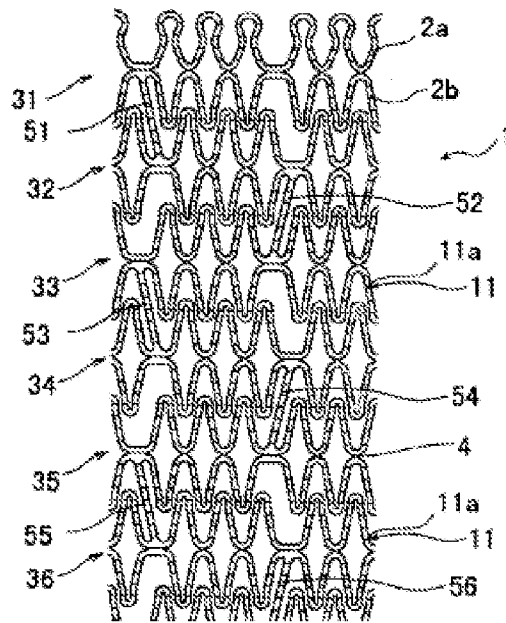


Figure 2 of the Specification shows a stent with “annular units 31, 32, 33, 34, 35, 36 . . . each consisting of a first wavy annular member 2a annularly formed of a wavy element . . . [and] a second wavy annular member 2b disposed in the axial direction of the stent 1 in such a way that the mountain thereof is proximate to a valley of the first wavy annular member 2a and annularly formed of a wavy element” (Spec. 5: 29 to 6: 5). “In this manner, one annular unit is constructed” (*id.* at 6: 28-29).

FF3 Figure 3 of the specification, reproduced below, is an enlarged view of the wavy annular members and the deformable portions, i.e., grooves 11a, 11, shown in Figure 2:

**FIG. 3**

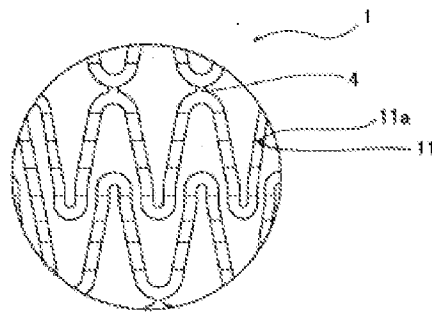
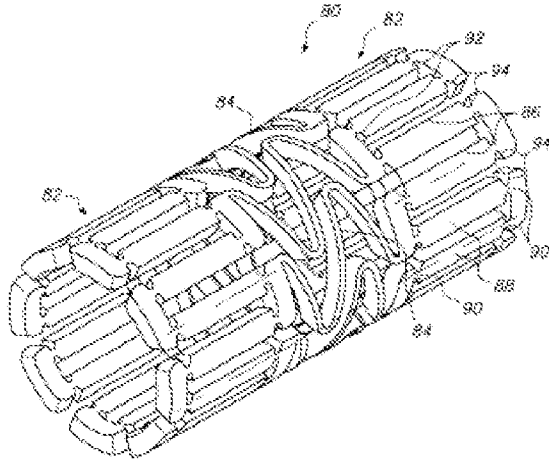


Figure 3 shows “the deformable portion [grooves 11a, 11] . . . formed on a bent portion of the wavy annular member” (*id.* at 8: 27-29). “The deformable portion is formed in such a way that when the deformable portion is prolonged, it continuously goes around the periphery of the device. That is, when the deformable portion is prolonged, it forms an endless annular configuration” (*id.* at 9: 20-23).

*Shanley*

FF4 Shanley discloses an implantable expandable medical device or “tissue supporting device” comprising a plurality of cylindrical tubes connected by S-shaped bridging elements (Shanley, col. 9, ll. 16-18).

FF5 Shanley’s Figure 4a, reproduced below, illustrates an axially bendable tissue supporting device:



**FIG. 4a**

Figure 4a illustrates Shanley's "tissue supporting device 80 [which] includes a plurality of cylindrical tubes 82 connected by S-shaped bridging elements 84 . . . [which] allow the tissue supporting device 84 to bend axially when passing through the tortuous path of the vasculature" (Shanley, col. 9, ll. 16-20).

FF6 Shanley doesn't disclose grooves on the surface of the stent, for any purpose.

*Palmaz*

FF7 Palmaz describes an implantable intravascular stent with "at least one groove disposed in the inner surface of the stent" to "increase the rate of migration of endothelial cells upon the inner surface of the stent after it has been implanted" (Palmaz 3: 16-17, 24-25).

FF8 Palmaz's Figure 8, reproduced below, is a plan view showing various types of grooves provided on the inner surface of an unexpanded intravascular stent:



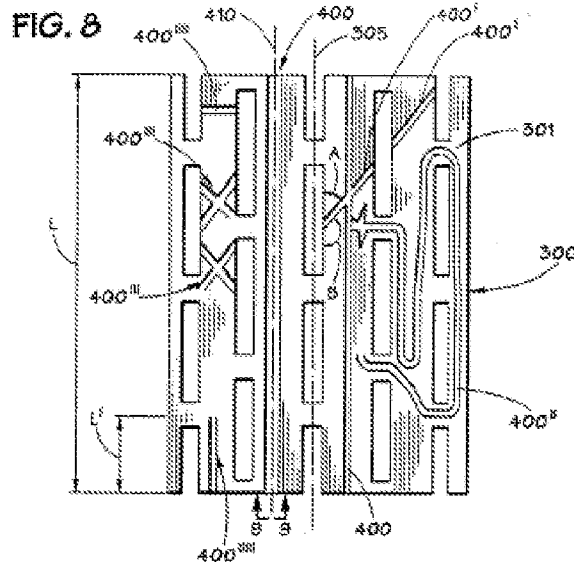


Figure 8 shows various types of grooves 400-400''', provided on the inner surface 301 of stent 300, "alone or in combination with each other, as desired, to provide whatever pattern of grooves is desired, including a symmetrical, or an asymmetrical, pattern of grooves" (Palmaz 8: 9-11).

#### PRINCIPLES OF LAW

When determining whether a claim is obvious, an Examiner must make "a searching comparison of the claimed invention - including all its limitations - with the teachings of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Moreover, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

## ANALYSIS

*Shanley and Palmaz: claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43*

The Examiner's position is that it would have been obvious to put grooves on Shanley's device because "Palmaz teaches the desirability of placing grooves on . . . a stent" (Ans. 6), "to aid in endothelial cell migration" (*id.*). The Examiner notes that Palmaz teaches that grooves 400-400'", shown in Figure 8, "could be provided alone or in combination with each other, as desired, including a symmetrical, or an asymmetrical pattern of grooves" (*id.* at 4-5). The Examiner finds that "a symmetrical pattern of grooves 400'" would result in an endless annular configuration" (*id.* at 5).

Appellant contends that neither Shanley nor Palmaz "disclose[s] or teach[es] at least the features of: 1) an implantable tubular device that has a deformable portion formed as a groove and configured such that when it is prolonged it forms an endless annular configuration [or a spiral configuration]; or 2) a deformable portion formed as a groove and formed on the bent portions of the wavy annular members" (App. Br. 10).

The Examiner is correct in that the law does not require elements of the prior art be combined for the same reason or advantage contemplated Appellant (*see e.g., In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992), and we agree with the Examiner that it would have been obvious to put grooves on Shanley's stent if only to promote endothelial cell migration.

Nevertheless, as Appellant points out, "there are many . . . symmetrical and asymmetrical configurations for the groove[s] . . . that would not 'read upon' Appellant's claims" (Reply Br. 3). That being the case, we disagree with the Examiner that Palmaz's comprehensive teaching that grooves 400-400'" may be provided anywhere on the inner surface of

the stent “alone or in combination with each other, as desired, to provide whatever pattern of grooves is desired, including a symmetrical, or an asymmetrical, pattern of grooves” (FF8) is an adequate suggestion or reason to place the grooves in an “endless annular configuration” or a “spiral configuration” as specifically required by the claims.

Comment [RML1]: KSR ?

*Shanley, Palmaz, and Alt: claims 14-19, 44, and 45*

The Examiner rejected claims 14-19, 44, and 45 as unpatentable over Shanley, Palmaz, and Alt. These claims depend directly or indirectly from claim 1 and additionally require the implantable device to carry a medicine, bioprosthetic material or a biosynthesis material.

The Examiner relies on Alt as evidence that it is conventional to coat implantable devices like those disclosed by Shanley and Palmaz with biologically active substances (Office Action mailed January 25, 2005, page 4).

Alt does not remedy the underlying deficiency in the Examiner’s proposed combination of Shanley and Palmaz.

#### CONCLUSIONS OF LAW

The Examiner has not established that the combined teachings of Shanley and Palmaz would have suggested providing grooves in an endless annular configuration or a spiral configuration on an implantable tubular device, wherein the tubular device comprises wavy annular members with bent portions.

SUMMARY

The rejection of claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43 under 35 U.S.C. § 103(a) as unpatentable over Shanley and Palmaz is reversed.

The rejection of claims 14-19, 44, and 45 under 35 U.S.C. § 103(a) as unpatentable over Shanley, Palmaz, and Alt is reversed.

REVERSED

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